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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CONNOLLY BOVE LODGE & HUTZ, LLP
P O BOX 2207
WILMINGTON, DE 19899

EXAMINER	
MCELWAIN, ELIZABETH F	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,457	CIRPUS ET AL.	
	Examiner	Art Unit	
	Elizabeth F. McElwain	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36 and 38-63* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 15-36 and 38-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 May 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-6 and 10-14, drawn to a process of producing compounds of formula I by introducing into a plant coding sequences for a delta-6 desaturase, a delta-6 elongase, a delta-5 desaturase, a delta-5 elongase and a delta-4 desaturase, in the reply filed on January 11, 2010 is acknowledged. Applicants also elected the following SEQ ID NOs for search purposes: SEQ ID NO: 11, 12, 27, 28, 41, 42, 83, 84, 193 and 194. The traversal is on the ground(s) that Applicants assert that the prior art cited by the Examiner does not teach all of the limitations of Group I in that the claims require that the seed of the plants have a content of at least 20% by weight of compounds of the general formula I based on the total lipid content, therefore the claims do not lack unity due to absence of a corresponding special technical feature. Applicants also argue that there would be no additional burden to search and examine Groups I-VII together.

2. The Examiner maintains that the presence of at least 20% of these compounds would be inherent in seeds produced by transforming a plant with coding sequences for a delta-6 desaturase, a delta-6 elongase, a delta-5 desaturase, a delta-5 elongase and a delta-4 desaturase. Furthermore, it is noted that the compound of the general formula I is written so broadly as to include compounds having as few as 9 carbons and up to 31 carbons, and as few as two double bonds and up to 6 double bonds, wherein this encompasses a multitude of fatty acids which may be found at that level regardless of expression of said coding sequences. Note Drexler at Table 1, where gamma linolenic acid (18:3) is present in wild type *Borago pygmea* at up to 28%, for

example. The Examiner maintains the search and examination of all of Groups I-VII would be an undue burden for the reasons set forth in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-36 and 38-63 are pending.

Claims 7-9, 15-36 and 38-63 are withdrawn as drawn to non-elected inventions.

Claims 1-6 and 10-14 are examined on the merits.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted that English translations of the foreign priority documents have not been provided.

Claim Objections

Claim 6 is objected to for reciting nonelected SEQ ID numbers: 53, 113, 54 and 114. Amendment of the claims to delete the nonelected subject matter is requested.

Specification

1. The disclosure is objected to because of the following informalities: it is unclear if there is a brief description provided for each of the drawings. A brief description must be provided for each drawing, and should be provided as one section of the specification.

2. In addition, the MPEP suggests a layout for the specification along with preferred headings for each section, which have not been used in the present specification.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3. The abstract of the disclosure is objected to because there is more than one paragraph.

Correction is required. See MPEP § 608.01(b).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-6 and 10-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 5-11 of copending Application No. 10/566,944. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2 and 5-11 of Application No. 10/566,944 is drawn to a method of making fatty acids of formula I in an organism by transforming the organism with a delta-6 desaturase, a delta-6 elongase, a delta-5 desaturase, a delta-5 elongase and a delta-4 desaturase, which would be obvious in view of the present claim drawn to a method having the same steps, wherein the level of compounds of formula I would be inherent in seeds produced by the same method. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-5 and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Drexler et al (J Plant Physiol 160 (7): 779-802, July 2003 in IDS).

8. The claims are drawn to a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 20% of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase. Claim 5 recites that the seed has at least 1% by weight of docosahexaenoic acid. It is noted that the specification does not define delta-5 elongase activity.

9. Drexler et al teach a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in a plant by introducing into the plant coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase (see pages 794-796 and Figure 6, for example), wherein the biosynthetic pathway is known and genes for each of these enzymes are cloned from numerous eukaryotic organisms and bacteria. Drexler et al also teach transformation of canola

(Brassica) with desaturase coding sequences (page 796, the last full paragraph) to produce polyunsaturated fatty acids (18:3). And the claimed percentages of formula I compounds and the claimed composition of substituents R^2 and R^3 would be inherent in seeds made by the same method.

10. Claims 1-5 and 10-14 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Kinney et al (US PGPub 20040172682 A1 in IDS, published September 2, 2004 with priority to provisional application filed February 12, 2003).

11. The claims are drawn to a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 20% or at least 27% (claim 4) of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase. Claim 5 recites that the seed has at least 1% by weight of docosahexaenoic acid. It is noted that the specification does not define delta-5 elongase activity.

12. Kinney et al teach a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in a plant by introducing into a soybean embryo coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase. See page 30, where the constructs pKR364 and pKR365 each comprise coding sequences for a delta-6 desaturase and a delta-5 desaturase; and pKR357 comprises coding sequences for a delta-4 desaturase and elongases from *Pavlova* and *Mortierella*. Kinney et al disclose at Table 10 on page 31 transformed somatic

embryos from soybean that comprise about 1-3% DHA and greater than 20% 18:3, and the claimed percent by weight of formula I compounds would be inherent in seeds produced by the same method, and wherein the elongases from *Pavlova* and *Mortierella* appear to have the same activities as delta-5 and delta-6 elongases given the production of DHA in the transformants. And the claimed percentages of formula I compounds and the claimed composition of substituents R^2 and R^3 would be inherent in seeds made by the same method.

13. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-6 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drexler et al (J Plant Physiol 160 (7): 779-802, July 2003 in IDS) taken with Geneseq Accession ABV74261 (Lerchl et al, March 28, 2003).

17. The claims are drawn to a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 20% of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase. Claim 5 recites that the seed has at least 1% by weight of docosahexaenoic acid. It is noted that the specification does not define delta-5 elongase activity.

18. Drexler et al teach a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in a plant by introducing into the plant coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase (see pages 794-796 and Figure 6, for example), wherein the biosynthetic pathway is known and genes for each of these enzymes are cloned from numerous eukaryotic organisms and bacteria. Drexler et al also teach transformation of canola (Brassica) with desaturase coding sequences (page 796, the last full paragraph) to produce polyunsaturated fatty acids (18:3). And the claimed percentages of formula I compounds and the claimed composition of substituents R^2 and R^3 would be inherent in seeds made by the same method, as stated above.

19. Drexler et al do not teach a delta-6 elongase of SEQ ID NO: 27 encoding SEQ ID NO: 28.

20. Geneseq Accession ABV74261 teaches a sequence 100% identical to a coding sequence for SEQ ID NO: 28.

21. Given the teachings of Drexler et al of the desirability of producing long chain polyunsaturated fatty acids in a plant by transforming a plant with genes encoding a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase, one of ordinary skill in the art would have been motivated to practice the same method by substituting other known sequences having the same activities, such as the delta-6 elongase from *Phaeodactylum* taught by Geneseq Accession ABV74261. And the particular R2 and R3 constituents and levels of polyunsaturated fatty acids would be the optimization of process parameters and would not confer patentable distinction to the claimed invention. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

22. Claims 1-6 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney et al (US PGPub 20040172682 A1 in IDS, published September 2, 2004 with priority to provisional application filed February 12, 2003).

23. The claims are drawn to a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 20% or at least 27% (claim 4) of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase. Claim 5 recites that the seed has

at least 1% by weight of docosahexaenoic acid. It is noted that the specification does not define delta-5 elongase activity.

24. Kinney et al teach a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in a plant by introducing into a soybean embryo coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase. See page 30, where the constructs pKR364 and pKR365 each comprise coding sequences for a delta-6 desaturase and a delta-5 desaturase; and pKR357 comprises coding sequences for a delta-4 desaturase and elongases from *Pavlova* and *Mortierella*. Kinney et al disclose at Table 10 on page 31 transformed somatic embryos from soybean that comprise about 1-3% DHA and greater than 20% 18:3, and the claimed percent by weight of formula I compounds would be inherent in seeds produced by the same method, and wherein the elongases from *Pavlova* and *Mortierella* appear to have the same activities as delta-5 and delta-6 elongases given the production of DHA in the transformants. And the claimed percentages of formula I compounds and the claimed composition of substituents R^2 and R^3 would be inherent in seeds made by the same method.

25. Kinney et al do not teach a delta-6 elongase of SEQ ID NO: 27 encoding SEQ ID NO: 28.

26. Geneseq Accession ABV74261 teaches a sequence 100% identical to a coding sequence for SEQ ID NO: 28.

27. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/
Primary Examiner, Art Unit 1638